

## **PEN NEEDLE AND SAFETY SHIELD SYSTEM**

### **FIELD AND BACKGROUND OF THE INVENTION**

5           **[00001]**           This application claims priority to PCT Application No. PCT/US01/23367 filed July 25, 2001, which claims priority to U.S. Provisional Application No. 60/222,454 filed August 2, 2000.

**[00002]**           The present invention relates to an improved pen needle and safety shield system particularly, but not exclusively, adapted for pen injectors. The safety shield system of this invention includes a retractable generally tubular shield which is spring biased to normally enclose the needle cannula of a pen needle dispenser, but which locks in the extended position enclosing the needle cannula following injection. Further, the double ended needle cannula assembly may be safely nested in the cup-shaped cap following injection for disposal.

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**[00003]**           Hypodermic syringes have been used for many years to deliver selected doses of fluids including liquid medicaments, inoculations, etc. to patients. However, many applications using hypodermic needles are self-administered, including, for example, insulin, anti-histamines, et cetera. The required manipulation of a standard prior art hypodermic syringe can be inconvenient, particularly where the injection is self-administered in a public environment. Medication delivery pens or pen injectors have therefore been developed to facilitate self-administration of injections. A typical pen injector includes a generally tubular body portion resembling a fountain pen which receives a vial of fluid, such as insulin, anti-histamines, et cetera, having a pierceable closure, such as a rubber septum. The pen needle includes a hub generally having a double ended needle cannula including a first end which extends into the body portion of the pen injector for piercing the closure of the vial and a second end used for self-injection of the fluid contained in

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the vial. The pen needle also generally includes a removable cup-shaped cap which encloses the second end of the needle cannula prior to use.

[00004] Various improvements in pen needles have been developed or proposed by the prior art since its introduction, including adjustable injection length pen needles as disclosed in U.S. Patent No. 5,944,700 assigned to the assignee of the present application and safety shield systems for such pen needles, wherein the shield is generally cup-shaped including an open end which receives the body portion of the pen needle and a generally closed end portion having a central opening which receives the second end of the needle cannula when the shield is retracted from a first position enclosing the second end of the needle cannula to a second position wherein the needle cannula is exposed for injection. The assembly may further include a spring that biases the shield to the normally enclosed first position prior to injection.

[00005] Various safety shield systems have also been developed or proposed by the prior art for conventional hypodermic syringes wherein a tubular shield is spring biased to enclose the needle cannula following injection and including safety shields which lock in the extended enclosed position following injection. Such safety shield systems for conventional hypodermic syringes are operated manually or are spring biased to extend the tubular shield and enclose the needle cannula following injection but all require additional action (active systems,) such as force, to activate as compared to the standard injection process. Hand manipulated safety shield systems may include spiral or complicated channel-shaped tracks on an inside surface of the shield which guide the shield during extension of the shield to enclose the needle cannula and lock the shield in the extended position. However, such complicated track systems may not always be reliable.

[00006] A safety shield system for pen needles has not yet been developed wherein the shield initially encloses the second end of the needle cannula prior to use, permits retraction of the shield for self-administration of the fluid in the pen needle dispenser and then extends and locks the shield in the extended position  
5 enclosing the needle cannula following use. It would also be desirable to simplify the operation of the shield to eliminate manual manipulation or rotational movement of the shield from the retracted position to a locked extended position.

[00007] One problem with other pen needle accessories, such as hidden needle adapters, has been potential needle sticks to the user during assembly of the  
10 accessory on the pen injector. Because the shield must be retractable for injection and the shield and cap assembly is typically threaded on the pen needle dispenser, the natural tendency of the user or patient is to press the cap toward the injector during assembly. This may cause the needle to pierce the cap and possibly puncture the user during assembly. Another problem associated with pen needles has been the safe  
15 disposal of the hub and double ended needle cannula. It would be most desirable to safely enclose both sharp ends of the needle cannula hub assembly to avoid inadvertent punctures during and following disposal. As will be understood, one end of the needle cannula may be enclosed in the cup-shaped cap; however, the other end is exposed following removal of the hub assembly from the pen injector.

20 [00008] The pen needle and safety shield system of this invention solves these problems by providing a safety shield which normally encloses the needle cannula prior to use, permits retraction of the safety shield during injection and automatically extends and locks the shield in the extended enclosed position following use. The pen needle of this invention also prevents retraction of the shield  
25 during assembly of the shield and needle cannula and hub assembly on the pen

injector. Further, the improved safety shield system of this invention permits safe disposal of the hub and double-ended needle cannula assembly following removal from the pen injector.

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### SUMMARY OF THE INVENTION

[00009] As set forth above, the improved safety shield system of this invention is particularly but not exclusively adapted for pen injectors. That is, although the safety shield system of this invention was specifically designed for use with pen injectors of the type described herein, the safety shield system of this invention may also be used with other devices including conventional hypodermic  
10 needle fluid delivery systems. For ease of description, however, the safety shield system of this invention will now be described as a component of a pen injector. As set forth above, such pen injectors generally include a tubular body portion adapted to receive a conventional vial for dispensing a fluid, such as insulin, anti-histamines, et  
15 cetera. A conventional pen needle dispenser further includes a needle cannula hub assembly wherein the hub is generally cup-shaped including a tubular portion having an open end which threadably receives the tubular end portion of the pen injector and a closed end portion which receives and secures the needle cannula. The tubular portion of the needle hub may be threadably or otherwise attached to the tubular end  
20 portion of the pen injector. The needle cannula extends through the end portion of the hub and includes a first end portion which extends into the body portion of the pen injector for piercing the closure in the vial and an opposed second end portion used for injection of a patient, including self-injection.

[00010] The improved safety shield system of this invention includes a  
25 generally tubular clip member preferably having a tubular body portion received

around the tubular hub portion of the needle hub assembly and a plurality of spaced laterally projecting resilient fingers. In the preferred embodiment of the safety shield system of this invention, the free ends of the resilient fingers are hook-shaped opening toward the body portion of the pen injector. The safety shield system further includes

5 a generally tubular recipricable shield having a first tubular portion surrounding the clip member and a second tubular portion normally surrounding the second end of the needle cannula. As described below, the shield is spring biased to normally extend the second portion of the shield around the needle cannula. The shield further includes a plurality of spaced axially extending inwardly opening channel-shaped

10 tracks on an inner surface of the shield which receive the resilient fingers of the clip member. During reciprocal motion of the shield as described below, the axially extending channel-shaped tracks guide the shield from a first position, wherein the shield second portion surrounds the second end of the needle cannula, to a second position, wherein the second end of the needle cannula is exposed for injection of a

15 patient. The safety shield system further includes a spring resiliently biasing the shield axially to normally extend the shield second portion to surround the second end of the needle cannula. Thus, during use of the pen injector, the health care worker or patient presses the end of the shield against the area to be injected, which retracts the shield to the second position against the force of the spring. In the most preferred

20 embodiment, the shield is cup-shaped including the first and second tubular portions described above and a generally closed end portion having a central opening which receives the second end of the needle cannula therethrough during injection. Following use, the spring automatically extends the shield to enclose the second end of the needle cannula.

[00011]

At least one of the channel-shaped tracks in the shield includes an opening spaced from but near the open end of the shield, and means is provided to prevent the free end of the resilient finger from being received in the opening during retraction of the shield from the first position enclosing the second end of the needle cannula to expose the needle cannula as described. Thus, the shield may be retracted to expose the second end of the needle cannula during injection, but the resilient finger will lock into the opening when the spring extends the shield to enclose the second end of the needle cannula following injection. The shield is thereby locked in the first position enclosing the second end of the needle cannula following injection.

10 In the preferred embodiment, wherein the free end of the resilient fingers are hook-shaped as described above, the hook-shaped portion of the finger is received through the opening and securely locks the shield in the closed position. In the most preferred embodiment, each of the channel-shaped tracks include an opening which receives and secures each of the locking fingers. The improved safety shield system of this

15 invention thus permits one retraction of the safety shield during injection and locks the safety shield to enclose the second end of the needle cannula following injection. Although various means may be utilized to prevent receipt of the locking fingers in the openings in the channel-shaped tracks during retraction of the safety shield to expose the needle cannula, a preferred embodiment includes a resilient detent or

20 finger portion in the tracks adjacent the opening which resiliently biases the fingers of the clip member inwardly, such that the resilient fingers of the clip member travel past the opening during retraction of the shield member to the second position as described above. Further, the resilient detents catch the hook-shaped end portions of the resilient fingers during extension of the shield, assuring locking of the shield in

25 the extended position following injection.

[00012] The preferred embodiment of the safety shield system of this invention further includes a removable cup-shaped cap which is received over the shield prior to use. As will be understood, the cap is then removed and the pen injector is ready for use as described above. However, the cap of the improved safety shield system of this invention may also be used to safely store and dispose of the double ended needle cannula. As described above, the second end of the needle cannula is protected following injection by the safety shield which is locked in the extended position surrounding the second end of the needle cannula. The needle cannula and safety shield system may then be safely stored in the cap for disposal by removing the needle cannula and safety shield assembly from the pen injector and inserting the first end of the needle cannula into the cup-shaped cap which is configured and adapted to receive and store the assembly for safe disposal. That is, the first end of the needle cannula is then located in the cup-shaped cap preventing exposure to the needle cannula and the second end portion is safely enclosed by the safety shield which is locked in the extended position protecting the second end of the needle cannula.

[00013] The safety shield system of this invention thus provides reliable operation and protection from the needle cannula. In the preferred embodiment, the generally tubular safety shield moves axially guided by the axially extending channel-shaped tracks as described above, thereby eliminating rotational movement of the shield or a complex track system. In the most preferred embodiment, the tubular body portion of the clip member includes a plurality of spaced axially extending radially projecting ribs which are received in axially extending grooves in the tubular portions of the shield, assuring axial movement of the shield during retraction and extension of the shield as described above. In the most preferred embodiment, the resilient fingers

of the clip member include a U-shaped portion integrally connected to the tubular portion of the clip member and hook-shaped free end portions as described above. This configuration provides additional resiliency for the hook-shaped end portions of the fingers. Further, the U-shaped portion of the fingers preferably open toward the generally closed end of the shield and the spring includes a first end received in the U-shaped portions of the fingers and a second end biased against the generally closed end of the shield assuring reliable movement of the shield.

[00014] The pen needle and safety shield system of this invention also prevents retraction of the shield during assembly of the safety shield system on the pen injector. As set forth above, one problem with the prior art pen needles has been potential piercing of the cap during threaded assembly of the cap and shield assembly on the pen dispenser thereby exposing the user to puncture. The cap of the improved safety shield system includes a plurality of radially inwardly projecting ribs which are received in the axially extending grooves in the tubular portion of the shield against the axially projecting ribs on the clip member. The grooves in the tubular portion of the shield preferably extend through the side wall of the shield from adjacent the generally closed end to the ribs. These internal ribs on the cap prevent retraction of the shield during threaded assembly of the cap and shield assembly on the pen injector, thereby preventing accidental puncture during assembly.

[00015] The pen needle and safety shield system of this invention thus permits normal operation of the safety shield to retract the shield during injection and automatically extends and locks the shield following injection to prevent inadvertent contact with the second end of the needle cannula. Further, as described above, the needle cannula assembly may then be safely stored in the cup-shaped cap or cover for disposal wherein the first end of the needle cannula is located in the cup-shaped cover

and the second end is protected by the safety shield. Other advantages and meritorious features of the pen needle and safety shield system of this invention will be more fully understood from the following description of the preferred embodiments, the appended claims and the drawings, a brief description of which  
5 follows.

### **BRIEF DESCRIPTION OF THE DRAWINGS**

[00016] Figure 1 is a side view of a preferred embodiment of the pen needle and safety shield system of this invention with the cap removed;

10 [00017] Figure 2 is a partial cross-sectional view of the pen needle and safety shield system of this invention;

[00018] Figure 3 is a side elevation partially cross-section of the safety shield assembly;

[00019] Figure 4 is a side cross-sectional view of the safety shield;

15 [00020] Figure 5 is a partial side cross-sectional view of Figure 1 in the direction of view arrows 5-5;

[00021] Figure 6 is a partial cross-sectional view similar to Figure 5 during use of the pen needle and safety shield assembly for injection;

[00022] Figure 7 is a partial side cross-sectional view similar to  
20 Figure 6 following injection; and

[00023] Figure 8 is a side cross-sectional view of the safety shield system following removal from the pen injector and assembly for safe storage.

### **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

[00024] As set forth above, the improved safety shield system of this  
25 invention is particularly but not exclusively adapted for pen injectors, such as the pen

needles available from Becton Dickinson & Company best shown at 20 in Figures 1 and 2. As will be understood, however, the safety shield system of this invention may also be used with other pen injectors of this general type and with conventional hypodermic syringes as described above.

5           **[00025]**       As described below, the safety shield 22 normally encloses the second end 38 of the needle cannula 34 as shown in Figure 2 and the safety shield assembly 23 is enclosed by a cup-shaped cap 24 as shown in Figure 1. The disclosed embodiment of the pen needle 20 includes an open end 26 which may include external ribs 28 to facilitate gripping of the pen needle 20 by the user for threaded attachment  
10 of the assembly to the pen injector as described below. As shown in Figure 2, the pen injector 20 receives a vial shown in phantom at 30 having a pierceable closure such as a rubber septum (not shown) in the open tubular end portion 31 of the vial. The pen injector 20 further includes a needle cannula and hub assembly 32 which includes a needle cannula 34 which extends through the hub member 40 to define a first end 36  
15 which extends into the pen injector to pierce a closure of a vial 30 or other container and a second opposed end 38 used for injection, including self-administration as described above. The hub 40 includes a tubular rim portion 42 which is preferably threadably received on the tubular end portion 44 of the pen injector 20 and a central  
( portion 46 which receives and secures the needle cannula 34. As will be understood  
20 by those skilled in this art, the needle cannula 34 includes a lumen or small passage therethrough for transferring fluid in the vial 30 to the user for self-injection or administration by a health care worker and the tubular rim portion 42 of the hub 40 may include internal threads for threaded receipt of the hub on the externally threaded rim portion 44 of the pen injector. Needle cannula and hub assemblies of this general

type are well known in this art and therefore no further description of the needle cannula and hub assembly or the pen injector are required.

[00026] The safety shield system of this invention includes a generally tubular clip member 48 having a tubular body portion 50 which is received around the tubular rim portion 42 of the needle hub member 40 as shown in Figure 2 and a plurality of laterally projecting resilient hook-shaped fingers 52. The clip member may be formed of a resilient polymeric material, such as polypropylene, such that the fingers are able to flex inwardly and resiliently flex outwardly as described below. Alternatively, the clip member 48 may be formed of a metal stamping. As shown in Figure 2, for example, the fingers 52 are supported on a U-shaped portion 54 which further improves the resiliency of the fingers as they flex inwardly and spring outwardly. The clip member further includes a plurality of circumferentially spaced radially extending ribs 56 which prevent rotational movement of the shield 22 and guide the shield during axial movement of the shield as described below.

[00027] The safety shield 22 is generally tubular having an open end 58 and preferably including a generally closed end 60 having an axial opening 62 therethrough which receives the second end 38 of the needle cannula 34 as described below. The shield 22 further includes a plurality of circumferentially spaced longitudinally or axially extending channel-shaped tracks 64 in an internal surface of the tubular portion of the shield which receives the hook-shaped fingers 52 and a plurality of circumferentially spaced axially extending slots or grooves 66 which receive the radial ribs 56 on the clip. As will be understood, the longitudinal axis of the safety shield 22 is coincident with the needle cannula 34. In the preferred embodiment, the axial channel-shaped tracks 64 each include a radial opening 68 which is generally adjacent to but spaced from the open end 58 of the shield. Each of

the axial channel-shaped tracks 64 also include an inwardly projecting resilient integral tang or finger portion 70 adjacent the opening 68 closest to the open end 58 as best shown in Figure 4. The resilient tangs or finger portions 70 resiliently bias the hook-shaped fingers 52 inwardly and preferably include a ledge 72 releasably retaining the shield 22 in the extended position prior to injection as shown in Figure 2 and further described below.

[00028] The safety shield system of this invention further includes a coil spring 74 biased between the clip member 48 and the generally closed end 60 of the shield resiliently urging the shield toward the extended position to enclose the second end 38 of the needle cannula 34 as shown in Figure 2. In the disclosed embodiment, the inside surface of the shield includes a plurality of circumferentially spaced radially projecting ribs 76 which centers the coil spring 74 in the shield. Finally, the cup-shaped cap 24 includes an open end 78 which receives the safety shield assembly 23 and needle cannula and hub assembly 32 as described below and a closed end 80. In the most preferred embodiment, the internal surface of the cap includes a plurality of radially projecting ribs which extend axially from adjacent the closed end 80 to the ends of the radial ribs 56 which prevent retraction of the safety shield 22 during assembly on the pen injector 20 as described below. The external surface of the cap may also include ribs 28 to assist in gripping the cap during assembly of the safety shield assembly 23 on the pen injector 20. The closed end 80 of the cap also includes an inwardly projecting dimple 86 which is received in the opening 62 of the shield centering the cap on the shield. Other details of the preferred embodiments of the safety shield assembly will be discussed below in the description of the assembly and operation of the disclosed embodiment of the pen needle and safety shield system of this invention.

[00029] First, the operation of the disclosed embodiment of the pen needle and safety shield system will now be described. One important advantage of the safety shield assembly of this invention is that the safety shield assembly 23 and the needle cannula and hub assembly 32 may be preassembled and supplied to the patient or end user as an assembly ready for use. The first step by the patient or end user is then to attach this assembly to the pen injector 20 by threading the tubular rim portion 42 of the needle hub assembly 32 on the tubular end portion 44 of the pen injector. As can be seen from Figure 2, the internal radial ribs 84 on the cap 24 which are aligned with the ribs 56 of the clip member 48 prevent inadvertent depression or retraction of the safety shield assembly 23 which could drive the second end 38 of the needle cannula 34 through the opening 62 of the shield and puncture the cap, which would expose the end user to the needle. This is an important improvement over prior pen needle injectors where the patient or health care worker could be inadvertently exposed to the needle during assembly. The vial 30 may be previously loaded into the pen injector 20 and the open end 26 may be closed by an end cap, such that the threaded assembly results in piercing the first end 36 through the closure, such as a rubber septum, in the open end 31 of the vial 30 as the tubular rim portion 42 of the needle hub is threaded onto the rim portion 44 of the pen injector. Alternatively, the vial 30 may be inserted into the pen injector following assembly.

[00030] The cap 24 is then removed from the assembly as shown in Figures 1 and 5. The pen needle and safety shield assembly of this invention is then ready for use.

[00031] As set forth above, the safety shield assembly 23 of this invention is particularly, but not exclusively, suitable for pen needle injectors typically used for self-administration of fluid or liquid drugs, vaccines or medicament,

such as insulin, anti-histamines, et cetera. During use, the patient simply depresses the generally closed end 60 of the safety shield against the body area to be injected as shown in Figure 6. As shown in Figures 2 and 5, the hook-shaped fingers 52 are releasably retained by the inwardly projecting tangs or finger portions 70 of the shield preventing inadvertent retraction of the shield and providing some resistance to movement of the shield during injection which is considered an advantageous feature of this invention. Further, the fingers 52 are resiliently biased inwardly, such that retraction of the shield when the generally closed end of the shield is pressed against the skin causes the fingers 52 to move over the openings 68 and move into the channel-shaped tracks 64 during initial retraction of the shield, exposing the second end 38 of the needle cannula which is received through the opening 62 of the shield, resulting in injection of the patient. Rotation of the shield relative to the needle cannula and hub assembly 32 is prevented by the ribs 56 which follow the axial slots or grooves 66 assuring axial movement of the shield.

15           [00032]       Following injection, the needle 38 is withdrawn from the patient and the shield 22 is simultaneously extended by the coil spring 74, such that the second end 38 of the needle cannula is never exposed. The shield is then extended axially as the needle is withdrawn because the hook-shaped fingers move in the axial channel-shaped track 64 and the radial ribs 56 move through the slots or grooves 66. 20   However, upon full extension of the shield to enclose the second end 38 of the needle, the hook-shaped fingers 52 are received through the openings 68 and the hook-shaped portion is received around the inwardly projecting tang 70, locking the shield in the extended position as shown in Figure 7. That is, the shield 22 cannot be retracted following injection to expose the second end 38 of the needle cannula.

[00033] The safety shield assembly 23 may then be removed from the pen injector 20 by unthreading the tubular rim portion 42 of the hub member 40 from the threaded tubular portion 44 of the pen injector 20 and safely disposed of directly into a sharps container or by reversing this assembly and inserting the assembly into the cup-shaped cap 24 as shown in Figure 8. The first sharp end 36 of the needle cannula is thus safely received in the cup-shaped cap 24 and the second end 38 of the needle cannula is protected by the safety shield 22, which is locked in the extended position, providing for safe disposal of the entire assembly. In the most preferred embodiment, the internal ribs 84 of the cap 24 provides an interference fit with the safety shield assembly 23, preventing inadvertent removal of the assembly from the cap and thus preventing inadvertent exposure to either end of the needle cannula 34 following disposal. In the disclosed embodiment, one or more of the ribs 84 include a ball-shaped end portion 90 which is received in a socket 92, securing the assembly in the cap 24 as shown in Figure 8.

[00034] The improved safety shield assembly of this invention thus provides several important advantages over the prior art, particularly pen injectors. First, the safety shield assembly 23 and cap 24 may be easily attached to the pen injector 20 without inadvertent retraction of the safety shield assembly 23 on the pen injector and piercing of the cap 24, exposing the needle and the patient. This safety feature is provided by the radial ribs 56 on the hub member 40, which engage the internal ribs 84 of the cap 24 preventing retraction of the shield during assembly. Upon removal of the cap, the pen injector may be easily utilized for self-injection by the patient by depressing the generally closed end 60 of the safety shield 22 against the area to be injected without ever exposing the second end 38 of the needle cannula 34 to view. Following injection, the safety shield 22 is automatically extended by the

spring to enclose the second end 38 of the needle cannula 34 and locked in the extended position by the resilient fingers 52 which extend into the openings 68 through the channel-shaped tracks 66. The hook-shaped fingers also lock over the resilient integral tangs 70. Following use, the safety shield assembly 23 and needle  
5 cannula and hub assembly 32 may be easily removed from the pen injector 20 by unthreading the tubular rim portion 42 of the hub member 40 from the tubular rim portion 44 of the pen injector, reversing the assembly, and inserting the first end 36 of the needle cannula into the cap 24, providing for safe disposal of the assembly wherein both ends of the double ended needle cannula are safely enclosed, preventing  
10 inadvertent contact with the needle.

[00035] As set forth above, the needle cannula and hub assembly 32 is assembled in the safety shield assembly 23 prior to receipt by the end user, wherein the hook-shaped fingers 52 are releasably retained by the ledge 72 of the inwardly projecting tangs 70 during assembly of the shield 22 on the clip member 48. The cap  
15 24 is assembled on the shield by disposing the inwardly projecting radial ribs 84 of the cap into the slots 66 in the shield as best shown in Figure 1, wherein the end portions 87 engage the ends of the radial rib portions 56 as best shown in Figure 2. The radial ribs in the disclosed embodiment include a chamfered end 57 which guides the ribs into the slot 66 and the radial ribs are connected to the tubular body portion  
20 by web portions 55. Further, the coil spring 74 is received between the radial ribs and the tubular body portion against the web portion 55 as shown in Figure 2. The radial ribs may thus be resiliently flexed inwardly during assembly. As set forth above, the clip member 48 may be formed of a resilient polymeric material, such as polypropylene or formed of a metal stamping. All of the components of the safety  
25 shield assembly 23 and the cap 24 are preferably formed of a sterilizable material

including a polymeric material which can be injection molded. Thus, a suitable material for the cap 24, shield 22 and clip member 48 is a sterilizable polypropylene.

[00036] Having described a preferred embodiment of the pen needle and safety shield system of this invention, it will be understood that various  
5 modifications may be made to the disclosed embodiment within the purview of the appended claims. For example, other locking means for locking the shield 22 in the extended position following injection may be utilized. Further, locking means may be provided within the cap for locking the safety shield assembly 23 within the cap following removal of the safety shield assembly from the pen injector 20 and storage  
10 of the assembly in the safety cap as shown in Figure 8, including interlocking ribs, etc. Further, certain improved features of the safety shield system of this invention may be utilized with conventional pen needle and shield assemblies, including, for example, the radial ribs 84 on the internal surface of the cap which prevent depression or retraction of the shield during assembly of the safety shield and cap on the pen  
15 injector as described above. Having described a preferred embodiment of this invention, we now claim the invention, as follows.